REMARKS

Claims 1-22 are pending in this application and have been examined. Claims 1-3, 7-10, 14-16, and 20-22 stand rejected. The allowability of Claims 4-6, 11-13, and 17-19 if rewritten in independent form is noted with appreciation. Claims 1-3 have been canceled without acquiescence in the Examiner's prior rejection of these claims or prejudice to applicants' right to pursue the subject matter of these claims in a separate application. Allowable Claim 4 has been amended to place Claim 4 in independent format. Claims 5-7 have been amended to depend from allowable Claim 4 and should also be in condition for allowance. No new matter has been introduced. Reconsideration and allowance of Claims 4-22 in view of the following remarks is respectfully requested.

The Objection to the Specification

The Examiner has objected to the specification for failing to comply to the requirements of 37 C.F.R. 1.821 through 1.825 on the basis that nucleic acid sequences are cited without their corresponding SEQ ID NOs. The specification has been amended to incorporate the missing SEQ ID NOs. Applicants respectfully request withdrawal of this objection.

The Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected Claims 1-3, 7-10, 14-16, and 20-22 under 35 U.S.C. 112, first paragraph, as not complying with the written description requirement. According to the Examiner, the claims encompass sequences that are not described in the specification and there is no record or description that would demonstrate conception of any nucleic acids other than those expressly disclosed. Applicants respectfully disagree. However, without acquiescing to the Examiner's position, Claims 1-3 have been canceled, Claim 4 has been amended to incorporate the limitations of independent Claim 1, and Claims 5-7 have been amended to depend from Claim 4. Accordingly, this rejection is believed to be moot with respect to Claim 7. Applicants

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

submit that Claims 8-10, 14-16, and 20-22 comply with the written description requirement for the following reasons.

The Federal Circuit has articulated that the standard for evaluating whether a patentee has fulfilled the written description requirement is that "[t]he disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described." *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 63 U.S.P.Q.2d 1609, 1616 (Fed. Cir. 2002). The Federal Circuit further clarified that "[i]t is incorrect, however, that all functional descriptions of genetic material fail to meet the written description requirement." *Id.* at 1613. The court noted that the written description requirement can be met by the disclosure of "functional characteristics when coupled with a known or disclosed correlation between structure and function," as is stated in the Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001) ("Written Description Guidelines"). *Id.* The Written Description Guidelines also state that "[t]he description need only describe in detail that which is new or not conventional." 66 Fed. Reg. at 1106.

More recently, the Federal Circuit stated that:

> In Enzo, we explained that functional descriptions of genetic material can, in some cases, meet the written description requirement if those functional characteristics are "coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." DNA and RNA are each made up of just four building blocks that interact with each other in a highly predictable manner. Each of those building blocks, or "nucleotides," is characterized by a unique "base": In the case of DNA, the four nucleotides include the bases adenine, thymine, cytosine, and guanine; RNA also includes adenine, cytosine, and guanine, but contains the base uracil in place of thymine. Adenine on one strand of DNA binds, or "hybridizes," to thymine on the other; in RNA, adenine binds to uracil; and in either DNA or RNA, cytosine binds to guanine. Given the sequence of a single strand of DNA or RNA, it may therefore have become a routine matter to envision the precise sequence of a "complementary" strand that will bind to it. University of Rochester v. G.D. Searle & Co., 69 U.S.P.Q.2d 1886, 1893-1894 (Fed. Cir. 2004) (internal citations omitted).

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

Claims 8-10, 14-16, and 20-22 are directed to methods for inhibiting the self-splicing reaction of Group I introns using oligonucleotides that mimic the 5' exon guide sequence of these introns. Specification, page 3, lines 12-14. Specifically, the inventors have discovered that a short oligonucleotide having a sequence that is essentially complementary to the internal guide sequence (IGS) of a Group I intron and containing phosphoramidate and/or thiophosphoramidate linkages in place of thioester linkages can inhibit the self-splicing reaction of Group I intron-containing RNAs, thereby preventing the formation of functional, spliced RNA products. Specification, page 6, lines 9-14. Specific embodiments described in the specification are directed to the use of oligonucleotides that inhibit the self-splicing of Group I intron-containing RNAs of *P. carinii* and *C. albicans*. See, e.g., specification, page 14, line 21 to page 24, line 25. However, one skilled in the art can readily visualize or recognize from the specification that the methods described therein are not limited to inhibiting the self-splicing of Group I intron-containing RNAs of *P. carinii* and *C. albicans*, but also to inhibiting the self-splicing of any other Group I-containing RNA.

For example, the specification clearly states that the inhibitory oligonucleotides "for any particular Group I intron will be designed based on the sequences of the IGS and the [external guide sequence, EGS] for that particular Group I intron. Preferably, the [inhibitory oligonucleotide] will be selected to have a sequence that is identical to the EGS, or a portion of the EGS." Specification, page 8, lines 32-35. Similarly, the specification states that "[t]he inhibitor oligonucleotide of the present invention is designed to be complementary to the IGS sequence. The inhibitor oligonucleotide will therefore be a 'mimic' of the EGS, that is, the inhibitor oligonucleotide will have essentially the same sequence as the EGS since the EGS is itself complementary to the IGS." Specification, page 8, lines 11-15.

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

As noted above, the Written Description Guidelines state that the specification "need only describe in detail that which is new or not conventional." The internal guide sequences for Group I introns are neither new nor unconventional. As noted in the specification, the internal guide sequences for numerous Group I introns have been previously described. Specification, page 8, lines 1-4. Additionally, the specification discloses methods for determining other internal guide sequences. Specification, page 8, lines 4-11. As also noted above, the Federal Circuit has stated that "[g]iven the sequence of a single strand of DNA or RNA, it may therefore have become a routine matter to envision the precise sequence of a 'complementary' strand that will bind to it." Because the specification describes (1) that inhibitor oligonucleotides are complementary to the IGS of Group I introns, (2) that the IGS of numerous Group I introns are previously known in the art, and (3) that the IGS of other Group I introns can be determined using methods that are well known in the art, one of skill in the art can readily visualize or recognize from the specification that the claimed invention encompasses compositions and methods for inhibiting the self-splicing of any other Group I-containing RNA.

Moreover, Claims 8-22 are not claiming a particular sequence, but a method of doing something with a particular type of sequence: in this case, a Group I intron. An over-simplified analogy would be a method of preventing agglomeration of proteins in a pharmaceutical composition, with claims directed to "a method of inhibiting agglomeration of a protein in solution by . . . [using the inventive method]." It is clear in this analogy that it would not be necessary to disclose the sequence of all proteins to which the method could be applied in order to comply with the written description requirement; it would be sufficient to provide enough working examples to support the breadth of the claim. Claims 8-22 are directed to a method of inhibiting the self-splicing of a Group I intron sequence. Applicants submit that the specification provides a full written description of these methods, and the working examples therein enable the

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

full scope of these claims. Just as in the protein agglomeration analogy, applicants should not be required to disclose the sequence of every Group I intron to which the methods of the invention could be applied.

For these reasons, applicants submit that Claims 8-10, 14-16, and 20-22 are in full compliance with the written description requirement. Accordingly, applicants respectfully request withdrawal of this ground of rejection.

Conclusion

In view of the foregoing remarks, applicants believe that Claims 4-22 are in condition for allowance. If any issues remain that may be expeditiously addressed in a telephone interview, the Examiner is encouraged to telephone applicant's attorney at 206-695-1783.

Respectfully submitted,

CHRISTENSEN O'CONNOR
JOHNSON KINDNESS PLLC

Karen Blöchlinger, Ph.D.
Registration No. 41,395
Direct Dial No. 206.695.1783

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Date: 11/23/04 Carole Gillespie

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LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100